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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,359	12/04/2001	Joel F. Holthaus	NI086-073	9781
7590 11/06/2003			EXAMINER	
Robert E. Hanson FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue Suite 2400 Austin, TX 78701			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/000,359	HOLTHAUS, JOEL F.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David H Kruse	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3/02</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 26 March 2002 has been considered, a signed copy is attached hereto.

### ***Claim Objections***

2. Claims 8 and 28 are objected to because of the following informalities:

At claim 8, the phrase "A tissue culture" should read -- The tissue culture -- in referring to claim 7.

At claim 28, line 1, "plants" is not in number agreement with claim 27 and should be -- plant --.

Appropriate correction is required.

### ***Deposit of Biological Material***

3. On page 34 of the Specification and at claims 1, 17 and 19, the Examiner notes Applicant's intention to deposit biological material. Applicant is reminded that an amendment to the specification and claims will be required upon deposit of biological materials to identify the deposit accession number (see 37 CFR § 1.809).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 6, 9, 10, 20, 23-25 and 29-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 6, the phrase "wherein said plant is male sterile" renders the claim indefinite because Applicant teaches that inbred corn line LH322 is male fertile, hence the metes and bounds of the claim are unclear.

At claim 9, line 2, the phrase "is capable of expressing" is indefinite because it is unclear what the metes and bounds of "capable of" is in the instant case (see page 7, paragraph 25, lines 2-4 of the specification). The limitation -- having -- is suggested.

At claim 10, line 2, the limitation "using the corn plant of claim 5" is indefinite because it is unclear what the metes and bounds of "using" are in the instant case. In addition, at lines 3-4, the phrase "for such a process" renders the claim indefinite because it is unclear what "process" this limitation is referring to.

At claims 9 and 10, the limitation "corn inbred LH322" renders the claim indefinite because said limitation is not an art recognized designation of a corn inbred and hence does not state the metes and bounds of the claimed invention.

At claims 20, 23, 25 and 29, the terms "high yield", "good stalk lodging resistance" and "above average stay green" are relative limitations and do not state the metes and bounds of the claimed invention. In addition, the limitation "adapted to...regions of the United States" appears to encompass any region of the United States, hence the metes and bounds of the claimed invention are unclear.

Claim 24 is indefinite because it is unclear where in the method of claim 19 that one of skill in the art is to practice the "plant tissue culture methods" or how such methods are to be utilized [sic] to derive progeny. Claim 25 is also indefinite because said claim does not obviate the indefiniteness of claim 24.

At claim 30, line 3, the limitation "using the corn plant, or its parts, of claim 2" is indefinite because it is unclear what the metes and bounds of "using" are in the instant case. Claim 31 is indefinite because such limitations as "restriction fragment length polymorphism enhance selection", genetic marker enhanced selection" and "transformation" do not further define using a corn plant as a source of breeding material, hence the metes and bounds of the claim are unclear. Claim 32 is also indefinite because it does not obviate the indefiniteness of either claim 30 or 31.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6, 12-18 and 20-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to corn progeny plants and transgenic corn plants having undisclosed identifying characteristics whereby only the characteristics of the inbred corn line LH322 are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 26-28 and 32, the effect of transgenes on the

physiological and morphological characteristic of a transgenic LH322 corn plant or progeny thereof, is not sufficiently described where by one of skill in the art could recognize the claimed corn plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. While claims 20, 23, 25 and 29 set forth at least two LH322 traits, the claimed corn plant is not adequately described because the terms used to describe the traits are relative terms, lacking a comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish LH322 progeny plants. Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the corn line LH322. Accordingly, there is a lack of adequate description of the claimed progeny plants, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

Claim 6 lacks adequate written description because Applicant describes inbred corn line LH322 as male fertile

8. Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant will be readily available to the public. It is noted that applicants intends to deposit inbred corn line LH322 as indicated on page 34 of the specification and claims 1, 17 and 19, but the full requirements for enabling the claimed invention have not been satisfied (see section (b) below).

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor

on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

Additionally, claims 6, 12-18 and 20-32 are not deemed adequately enabled because Applicant has failed to adequately teach one of skill in the art how to make and use progeny plants of the exemplified inbred corn line LH322 as broadly claimed.



See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Claim 6 is not deemed enabled for the reasons given supra, inbred corn line LH322 is male fertile.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences conferring a multitude of traits to a transgenic corn plant. No guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been

provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny, or their use.

Hunsperger *et al* (1996, U.S. Patent 5,523,520), Kraft *et al* (2000, Theor. Appl. Genet. 101:323-326), and Eshed *et al* (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger *et al* teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger *et al* teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft *et al* teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft *et al* teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed *et al* teach that in plants, epistatic genetic

interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Applicant has provided limited guidance for how to make and use the inbred maize plant designated LH322 in the instant specification. The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large  $F_2$  or  $S_0$  population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary

qualities (column 4, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the trait of grain yield of the parental inbred lines of a hybrid maize plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed maize plants and methods of making a maize plant using a second or filial non-exemplified maize plant produced from Applicant's exemplified hybrid maize plant. At claims 20, 23, 25 and 29, the terms "high yield", "good stalk lodging resistance" and "above average stay green", for example, are regulated by multiple, non-exemplified genes and that Applicant has failed to teach one of skill in the art how to make the claimed maize plants, even such maize plants having at least 50% of its ancestral alleles from LH322, because one of skill in the art could not predictably identify such a plant without undue trial and error experimentation.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds.

***Claim Rejections - 35 USC § 102/103***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 12-16, 20, 22, 23, 25, 29 and 32 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kevern, U.S. Patent 5,850,009, issued 15 December 1998.

Kevern discloses an inbred corn line designated PH0HC. Said PH0HC inbred corn line inherently discloses such relative traits as "good yield", "above average stay green" and "good stalk lodging resistance" (see for example, columns 13-16). Applicant should also note that because the limitations set forth in the claims lack a comparative basis as set forth in the 112 second paragraph rejection above, these limitations are interpreted by the Office to be identical to those taught by Kevern in the instant reference. While the inbred corn line of Kevern is designated PH0HC and the parent corn variety of the instant claims is designated LH322, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed LH322-derived plants from those "derived" from the prior art inbred corn plant (see for example Kevern, claim 10).

Kevern does not specifically disclose a method of producing corn plants using inbred corn line LH322 as a parent in an unspecified number of crosses with unspecified second parents.

The hybrid corn seed and hybrid corn plant of claims 12 and 13 would have been *prima facie* obvious to one of skill in the art at the time of applicant's invention because, depending upon what second inbred corn plant one of skill in the art had selected, the resulting corn seed and progeny could be genetically, morphologically and physiologically indistinguishable from that of the instant claims. Similarly, the corn seed of claim 14 and the F1 hybrid seed and plant of claims 15 and 16 would have been obvious in view of the teachings of the Kevern reference. The LH322-derived corn plant of claims 20, 22, 23, 25, 29 and 32 would also have been obvious in view of the Kevern reference because again, depending upon what second corn plant one of skill selects in producing said "derived" corn plant, the resulting progeny could be genetically, physiologically and morphologically indistinguishable from that of the claimed LH322-derived corn plant, given the loss of LH322-derived genetic material with each outcross to a non-LH322 parent. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

12. Claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kevern, U.S. Patent 5,850,009, issued 15 December 1998, in view of Lundquist *et al*, U.S. Patent 5,508,468, issued 16 April 1996.

The teachings of Kevern are discussed *supra*.

Kevern does not teach a transformed inbred PH0HC corn plant or progeny thereof.

Lundquist *et al* teach how to produce transformed fertile corn plants and how to produce transgenic progeny from said transformed corn plants.

It would have been prima facie obvious to one of ordinary skill in the art at the time of Applicant's invention to transform inbred corn line PH0HC as taught by Kevern to comprise a useful transgene as taught by Lundquist *et al*, and to produce progeny from said transformed inbred corn line PH0HC. Given the teachings of Lundquist *et al*, one of ordinary skill in the art would have been motivated to transform inbred corn line PH0HC to comprise a transgene conferring herbicide resistance as taught in Table 1, columns 11-12, of Lundquist *et al*, and one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success given the teachings of Lundquist *et al*. As outlined above, crossing a transformed PH0HC corn plant with another corn line, one of ordinary skill in the art would not be able to distinguish such a cross from that of the instant claim.

**Conclusion**

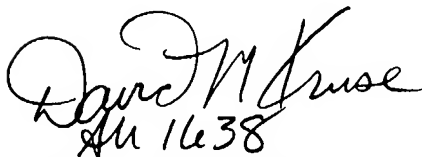
13. Claims 1-11, 17-19, 21, 24, 26, 27, 30 and 31 are free of the prior art, which neither teaches nor fairly suggest inbred corn line LH322 or method of using said corn line.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "David H. Kruse", with the number "1638" written below it.

David H. Kruse, Ph.D.  
30 October 2003